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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,946	03/24/2000	Frank R. Ruderman	MBHB00-203	1964

20306 7590 06/15/2005

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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/534,946

Applicant(s)

RUDERMAN ET AL.

Examiner

Carolyn M. Bleck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-28 and 38 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 22-28, and 38 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 29 March 2005.

Claims 22-28 and 38 are pending. Claims 22-27 have been amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 22, 24-28, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) in view of Otvos (6,576,471) and Bambeck (5,589,104).

(A) Claims 28 and 38 have not been amended, and are rejected for the same reasons given in the previous Office Action (12/27/04).

(B) Claims 22 and 24-27 have been amended to depend on claim 38. These amendments do not affect the scope and breadth of the claim as originally presented

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and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action (12/27/04).

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580), Otvos (6,576,471), and Bambeck (5,589,104) as applied to claim 37, and further in view of Surwit et al. (6,024,699).

(A) Claim 23 has been amended to depend on claim 38. These amendments do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action (12/27/04).

Declaration filed under 37 CFR 1.132

(A) The declaration under 37 CFR 1.132 filed 29 March 2005 is insufficient to overcome the rejection of claims 22-28 and 38 based upon Otvos as set forth in the last Office action because:

Applicant provides a declaration filed by David Shewmake. The affidavit is intended to show unexpected and valuable clinical results.

In response to Applicant's declaration, the Examiner respectfully submits that the declaration is not commensurate in scope with the claims. According to MPEP 716.02(d), the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In this case, Applicant has

provided evidence that "the method of Otvos described in the patent is not capable of determining in excess of 40% of subjects with normal HDL and LDL levels who are in need of treatment based on subparticle analysis described and claimed in the above application and which uses a next generation and thus more discriminating technology, "segmented gradient gel electrophoresis" (see page 2 of the Declaration filed 29 March 2005). The Examiner respectfully submits that claim 38 does not recite the technology of "segmented gradient gel electrophoresis." If Applicant intends to distinguish over the prior art based on this feature, it is suggested that Applicant amend the claims to include this feature.

Further, Applicant discusses at pages 2-3 of the Declaration filed 29 March 2005 that the NMR technology of Otvos only reports 2 subclasses of HDL and 2 subclasses of LDL, yet Applicant's invention reports more than 2 subclasses. The Examiner respectfully submits that all claim 38 requires is "subclassess of LDL particles and subclassess of HDL particles." There is no requirement that there be a certain number of subclassess. Thus, the Examiner respectfully submits that if Applicant intends to distinguish over the prior art based on the types of subclassess that are used, Applicant should amend the claims to include this feature.

Response to Arguments

5. Applicant's arguments filed 27 December 2004 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear in the response filed 27 December 2004.

(A) As Applicant fails to provide any further arguments other than the reliance on Declaration evidence that is ineffective to remove the prior art for the reasons given above, the rejections are hereby maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9306 or (703) 872-9326 [Official communications]

(703) 872-9327 [After Final communications labeled "Box AF"]

(571) 273-6767 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

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June 7, 2005

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A handwritten signature in black ink, appearing to read "Alexander Kalinowski". The signature is fluid and cursive, with a large loop at the end.

ALEXANDER KALINOWSKI
PRIMARY EXAMINER